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DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration
300 Pearl Street, Suite 100
Buffalo, NY 14202

March 27, 2003

WARNING LETTER NYK 2003-18

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Dale F. Beaver, Co-owner
Beavers Dairy Farm
3786 Kirk Road
Randolph, New York 14772

Dear Mr. Beaver:

An investigation performed by U.S. Food and Drug Administration Investigators Linda M. Sacco and Michael W. Burd included an inspection of your dairy farm on December 17, 2002, January 6 and 8, 2003 and February 19, 2003. The investigation confirmed that you offered a cow for sale for slaughter as food in violation of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). In addition, your extra label usage, and the illegal tissue residues that resulted, caused the drug product [redacted] (flunixin meglumine) to become adulterated within the meaning of Section 501(a)(5) of the Act.

A dairy cow bearing farm tag 2292 was treated for pain at your farm. Treatment included administration of daily 20 cc intramuscular injections of [redacted] (flunixin meglumine), for up to 3 days. The cow was subsequently offered for sale for human food on October 9, 2002, through [redacted] USDA analysis of samples collected from that animal on October 10, 2002, at [redacted] identified the presence of .5170 parts per million (ppm) flunixin in liver tissue.

A tolerance of 0.125 ppm has been established for residues of flunixin in cattle liver (Title 21 Code of Federal Regulations 556.286). However, as stated on the drug label, [redacted] is not approved for use in lactating or dry dairy cattle. The presence of flunixin at the reported level in edible tissue from a lactating or dry dairy cow causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

Our investigation also found that you hold animals under conditions whereby medicated animals bearing potentially harmful drug residues are likely to enter the food supply. You lack an adequate system for assuring that drugs are used in a manner not contrary to the directions contained in the labeling, and for assuring that animals medicated on your farm have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. For example, you lack adequate written treatment records for veterinary drugs administered to your herd. Such records would identify the drugs administered, the treatment date, the identification of the animal treated, the dosage administered, the route of administration, the individual administering the medication, and the withdrawal times for milk and beef. Food from animals held under such conditions is adulterated within the meaning of Section 402(a)(4) of the Act.

In addition, you are adulterating the veterinary drug [redacted] (flunixin meglumine) [redacted] within the meaning of Section 501(a)(5) of the Act, when you administer it to lactating or dry dairy cattle. [redacted] becomes adulterated when you fail to use it in accordance with its labeled instructions, or in compliance with extralabel use regulations. Use of this drug contrary to its labeled instructions, resulting in a residue which may present a risk to public health and which is above an established tolerance, causes the drug to be unsafe within the meaning of Section 512 of the Act.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice. This may include seizure or injunction.

This letter is not intended to be an all-inclusive list of violations. As a producer of animals offered for use as food, you are responsible for ensuring that your overall operation and the foods you distribute are in compliance with the law.

USDA analysis of tissue samples collected from two additional cows from your farm also revealed illegal drug residues. These include a cow bearing ear tag 2162 sold August 7, 2002, through [redacted] USDA analysis of samples collected from that animal on August 9, 2002, at [redacted] identified the presence of 3.96 ppm sulfamethazine in liver tissue and 0.11 ppm sulfamethazine in muscle tissue. A tolerance of 0.1 ppm has been established for residues of sulfamethazine in uncooked edible tissues of cattle (Title 21 Code of Federal Regulations 556.670). Another cow, bearing farm tag 1887, was sold August 21, 2002, through [redacted] USDA analysis of samples collected from that animal on August 22, 2002, at [redacted] identified the presence of 1.66 ppm gentamicin in kidney tissue. There is no permitted level for residues of gentamicin in edible tissues of cattle.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you caused the adulteration of an animal that was sold and subsequently offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

Please notify this office in writing, within 15 working days, of the steps you have taken to prevent a recurrence of similar violations. Your response should be directed to James M. Kewley, Compliance Officer, at the above address.

Sincerely,

Jerome G. Woyshner
District Director

cc: Donald Beaver, Co-owner
Beavers Dairy Farm
3786 Kirk Road
Randolph, New York 14772

cc: Duane Beaver, Co-owner
Beavers Dairy Farm
3786 Kirk Road
Randolph, New York 14772